K002356

OCT 3 0 2000

510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Sulzer Orthopedics® Natural-Knee® II Patellofemoral Joint Prosthesis.

Submitter:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	August 1, 2000
Contact Person:	Mitchell A. Dhority Manager, Regulatory & Clinical Affairs
Classification Name:	21 CFR 888.3540 - Knee joint patellofemoral polymer/metal semiconstrained cemented prosthesis
Common/Usual Name:	Patellofemoral Joint Prosthesis
Trade/Proprietary Name:	Natural-Knee® II Patellofemoral Joint Prosthesis

PRODUCT DESCRIPTION

The purpose of this submission is to gain marketing clearance for the Natural-Knee II Patellofemoral Joint Prosthesis. This device is identical to the previously cleared product (K962190) which was withdrawn from the market upon call for PMA's. Now that this classification of devices have been reclassified and a Final Rule issued (Docket 99N-0035), Sulzer Orthopedics now wishes to re-enter the market with the device.

The Patellofemoral Joint Prosthesis offers a viable surgical alternative to the more invasive total knee arthroplasty by replacing only those areas of the knee joint which have been affected by the disease process/injury (e.g., patella, trochlear groove).

All design aspects are the same as the previously cleared device. The femoral component is manufactured from either cast cobalt chromium alloy (ASTM F75) or wrought cobalt chromium alloy (ASTM F1537). The design is asymmetric (left and right components) and is available in four sizes (0-3). The anterior surface of the component is highly polished and features a deep trochlear groove which closely replicates the natural anatomic features of the distal femur. The geometry of the trochlear groove is also identical to that of the currently marketed Natural-Knee II System femoral component, allowing use of one of the Natural-Knee II patella components (all-poly or metal backed). When properly implanted, the design of this component allows for optimal patellar tracking, increased contact area, and increased resistance to subluxation. The posterior surface of the Patellofemoral Joint Prosthesis employs cement pockets and two fixation pegs for enhanced stability of the prosthesis when cemented into the femur. The posterior surface is also grit blasted to facilitate interdigitation with bone cement.

The design of this device is such that minimal bone is removed upon implantation. This feature facilitates conversion to total knee arthroplasty if the disease process becomes more advanced and requires further treatment.

SPECIFIC DIAGNOSTIC INDICATIONS

The Natural-Knee II Patellofemoral Joint Prosthesis is intended for cemented use for treatment of the following:

1. Patients with osteoarthritis in the distal femur and patella.
2. Patients with a history of patellar dislocation or patellar fracture.
3. Those patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release, etc.) where pain, deformity, or dysfunction persists.

SUBSTANTIAL EQUIVALENCE

Substantial equivalence is based on comparison to the previously cleared Natural-Knee II Patellofemoral Joint Prosthesis (K962190) and other previously distributed competitive PFJ designs including the following:

- Bechtol Type I (Smith & Nephew Orthopedics, formerly Richards Medical)
- Bechtol Type II (Smith & Nephew Orthopedics, formerly Richards Medical)
- Lubinus Patella Glide (Waldemaar Link)

These devices are similar in terms of design features and materials. Additionally, the subject and predicate devices share similar indications for use. The subject device, like the predicate devices, are used generically in the treatment of arthritis of the patella/patellar groove where total knee replacement is not warranted.

Testing did not raise any new issues of safety or effectiveness and indicated that this device should provide performance equivalent to commercially marketed products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2000

Mr. Mitchell A. Dhority, RAC
Manager, Regulatory & Clinical Affairs
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K002356
Trade Name: Natural Knee II Patellofemoral Joint Prosthesis (PFJ)
Regulatory Class: II
Product Code: KRR
Dated: August 1, 2000
Received: August 2, 2000

Dear Mr. Dhority:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002356

Device Name: Natural-Knee® II Patellofemoral Joint Prosthesis

Indications for Use:

The Natural-Knee II Patellofemoral Joint Prosthesis is intended for cemented use for treatment of the following:

1. Patients with osteoarthritis in the distal femur and patella.
2. Patients with a history of patellar dislocation or patellar fracture.
3. Those patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release, etc.) where pain, deformity, or dysfunction persists.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002356

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)